

Serial. No. 09/911,051

### REMARKS

#### Status of the Claims

Claims 1-17, 19, 21-29 and 31-36 are presently pending.

Claims 33-36 have been added above. Support for a medical device selected from a ureteral stent and a urethral catheter in new claim 33 can be found, for example, in original claim 18. Support for a reservoir which is in the form of a tubular medical device portion (e.g., a stent body or a catheter tube) in claims 34-36 can be found, for example, in Fig. 2 and in the associated discussion in the specification.

#### Rejection of claims 1, 5, 7-8, 10-11, 14, 21-22, 27-28 and 31-32 under 35 U.S.C. §102

Claims 1, 5, 7-8, 10-11, 14, 21-22, 27-28 and 31-32 are rejected under 35 U.S.C. §102(b) as anticipated by EP 0 879 595 A2 to Schneider (USA) Inc. This rejection and its supporting remarks are respectfully traversed.

Specifically, claims 1, 5, 7-8, 10-11, 14, 21-22, 27-28 and 31-32 are all directed to medical devices having a reservoir, which reservoir comprises an antimicrobial agent disposed within a polymer matrix. A surfactant region is disposed over the reservoir at an outer surface of the medical device. The reservoir is adapted for the long-term release of the antimicrobial agent from the polymer matrix. As defined in paragraph [0024] of the present specification, long term release is release over a period of at least three months.

Such a device is not described in Schneider (USA) Inc., which instead describes a device that provides release on the order of several days. See, e.g., Fig. 1 of Schneider (USA) Inc., in which release is measured out to 8 days, and Table 6a, which sets forth release data at 11 days.

Hence, claims 1, 5, 7-8, 10-11, 14, 21-22, 27-28 and 31-32 are novel over Schneider (USA) Inc. for at least this reason. Reconsideration and withdrawal of the rejection of claims 1, 5, 7-8, 10-11, 14, 21-22, 27-28 and 31-32 under 35 U.S.C. §102(b) are therefore respectfully requested.

Serial. No. 09/911,051

**Rejection of Claims 1-13, 15-17, 19, 23-26, 29, 31 and 32 under §103(a)**

**Claims 15, 17, 19 and 23-25**

Claims 15, 17 and 19 are rejected under 35 U.S.C. §103(a) as obvious over Schneider (USA) Inc. Claims 23-25 are also rejected under 35 U.S.C. §103(a) as obvious over Schneider (USA) Inc. These rejections are respectfully traversed for at least the following reasons.

Each of claims 15, 17, 19 and 23-25 is directed to a medical device having a reservoir that comprises an antimicrobial agent disposed within a polymer matrix. A surfactant region is disposed over the reservoir at an outer surface of the medical device. The reservoir is adapted to release the antimicrobial agent from the polymer matrix over a period of at least three months.

As noted above, Schneider (USA) Inc. does not describe a reservoir which is adapted for the long term release of an antimicrobial agent over a period of at least three months. To make up for this lack of disclosure, the Office Action states that catheters, stents and shunts for urinary treatment are well known in the art, and they are commonly used in patients for extended periods of time.

However, even assuming solely for the sake of argument that this is so, it is respectfully submitted that one of ordinary skill in the art upon reviewing Schneider (USA) Inc. would nonetheless *not* have been motivated to provide a medical device with a reservoir that is adapted to release the antimicrobial agent from the polymer matrix over a period of at least three months, absent hindsight afforded by the present invention.

In particular, as seen from Fig. 1 and its accompanying discussion in paragraph [0022] of the specification, the surfactant and antimicrobial agent of the present invention work more or less in series, with the surfactant initially providing the bulk of the anti-bacterial effect by resisting adherence of living bacteria (as well as dead bacteria and host protein). Unfortunately, due to degradation of the surfactant, the efficacy associated with the surfactant-modified surface decreases over time. The antimicrobial agent, however, eventually reaches the surface of the medical device to make up for the surfactant's loss in efficacy, preventing living bacteria from actively colonizing the medical device. Due

Serial. No. 09/911,051

to the long-term release characteristics of the reservoir that contains the antimicrobial agent, the antimicrobial effect is a sustained one.

In contrast with the present invention, the surfactant and drug in Schneider (USA) Inc. work in tandem with one another. Specifically, an ionically charged surfactant is used in Schneider (USA) Inc. to delay release of an oppositely charged drug. See, for example, page 3, lines 51-54 of Schneider (USA) Inc.:

In accordance with the present invention, negatively charged drugs contact positively charged surfactants to form a complex. Once the complex is formed, the solubility of the drug in body fluid is significantly reduced. Thus, the release rate of the drug in the body fluid is decreased. Similarly, positively charged drugs can form complexes with negatively charged surfactants to achieve similar results.

Hence, in contrast to the presently claimed invention, Schneider (USA) Inc. teaches those of ordinary skill in the art to delay release through the use of an ionic-surfactant-containing layer, rather than through varying the release characteristics of the polymeric reservoir layer that is disclosed therein.

Conversely, let us assume for the sake of argument that a person of ordinary skill in the art would have been motivated to modify the polymeric reservoir layer of Schneider (USA) Inc. so as to provide long-term (i.e., at least 3 months) drug release. In this scenario, it is respectfully submitted that the person of ordinary skill would have at the same time been motivated to dispense with the surfactant-containing layer. In this regard, as noted above, the surfactant-containing layer is used in Schneider (USA) Inc. to form a complex with the drug, thereby delaying release. As a result, upon modifying the polymeric reservoir layer to provide long-term release, the need for the surfactant-containing layer would have been eliminated. Accordingly, one of ordinary skill in the art would not have gone to the time, expense, etc. of including such a layer.

For at least the above reasons, it is respectfully submitted that claims 15, 17, 19 and 23-25, are unobvious in view of Schneider (USA) Inc.

Serial. No. 09/911,051

**Claims 2-4, 16 and 26**

Claims 2-4, 16 and 26 are rejected under 35 U.S.C. §103(a) as obvious over Schneider (USA) Inc. in view of Velraeds et al. and Millsap et al. Velraeds et al. and Millsap et al., which are cited in the Office Action for their disclosure concerning biosurfactants, however, do not make up for the above noted deficiencies in Schneider (USA) Inc. For at least this reason, reconsideration and withdrawal of the rejection of claims 2-4, 16 and 26 under 35 U.S.C. 103(a) as obvious over Schneider (USA) Inc. in view of Velraeds et al. and Millsap et al. are respectfully requested.

**Claims 5-6 and 17**

Claims 5-6 and 17 are rejected under 35 U.S.C. §103(a) as obvious over Schneider (USA) Inc. in view of Vacheethasane. However, Vacheethasane, which is cited in the Office Action for its disclosure concerning surfactant polymers, does not make up for the above noted deficiencies in Schneider (USA) Inc. For at least this reason, it is respectfully submitted that claims 5-6 and 17 are unobvious over Schneider (USA) Inc. in view of Vacheethasane. Accordingly, reconsideration and withdrawal of the rejections of these claims under 35 U.S.C. 103(a) are respectfully requested.

**Claims 9, 12 and 29**

Claims 9, 12 and 29 are rejected under 35 U.S.C. §103(a) as obvious over Schneider (USA) Inc. in view of BD WO 00/32168. BD, which is cited in the Office Action for its disclosure concerning antimicrobial agents, does not make up for the above noted deficiencies in Schneider (USA) Inc. For at least this reason, it is respectfully submitted that claims 9, 12 and 29 are unobvious over Schneider (USA) Inc. in view of BD. Accordingly, reconsideration and withdrawal of the rejections of these claims under 35 U.S.C. 103(a) are respectfully requested.

**Claims 1, 5, 7-8, 10-13 and 31-32**

Claims 1, 5, 7-8, 10-13 and 31-32 are rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,344,411 to Domb et al. in view of Schneider (USA) Inc.

Serial. No. 09/911,051

Domb et al. is cited in the Office Action for its disclosure of tubular medical devices that include coatings with dissolved iodine for the sustained release of iodine.

See, e.g., col. 16, lines 8-16 of Domb et al.:

By changing the thickness of the polymer coating and by using more than one polymer coating (e.g. using a combination of polyurethane-iodine matrix or polyurethane-iodine complexes, with a second coating of polyurethane-iodine complex or uniodized polymer), the amount and duration of iodine release can be programmed at the time of the coating. Using this approach, the duration of iodine release can be sustained for up to several months.

The Office Action concedes, however, that Domb et al. fails to include a surfactant region, and turns to Schneider (USA) Inc. to make up for this deficiency in Domb et al., alleging that it would have been obvious to incorporate the surfactant layer of Schneider (USA) Inc. over the polymer coating of Domb et al. It is respectfully submitted, however, that this is not the case.

For example, as discussed in more detail above, Schneider (USA) Inc. employs an ionic surfactant to form a complex and prolong drug release. Consequently, the employment of such a surfactant would be rendered superfluous by the presence of a matrix with a multi-month release profile. Hence, one of ordinary skill in the art would not have been motivated to provide the surfactant layer of Schneider (USA) Inc. over the polymer coating of Domb et al. as alleged in the Office Action.

For at least the above reasons, it is respectfully submitted that claims 5-6 and 17, 1, 5, 7-8, 10-13 and 31-32 are unobvious over Domb et al. in view of Schneider (USA) Inc. Accordingly, reconsideration and withdrawal of the rejection of these claims under 35 U.S.C. 103(a) are respectfully requested.

#### CONCLUSION

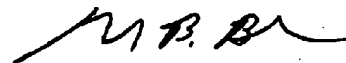
Applicants submit that claims 1-17, 19, 21-29 and 31-36 are presently in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, the Examiner is requested to telephone the Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues in this case.

Serial. No. 09/911,051

FEES

The Office is authorized to charge the additional claims fee as well as any other fees required to deposit account number 50-1047.

Respectfully submitted,



David B. Bonham  
Registration No. 34,297

Attorney for Applicant  
Mayer Fortkort & Williams, PC  
251 North Avenue West, 2<sup>nd</sup> Floor  
Westfield, NJ 07090  
Tel.: 703-433-0510  
Fax: 703-433-2362

Certificate of Facsimile Transmission

I hereby certify that this document and any document referenced herein are being sent to the United States Patent and Trademark office via Facsimile to: 703-872-9302 on Nov. 12, 2003.

David B. Bonham

(Printed Name of Person Mailing Correspondence)

\_\_\_\_\_  
(Signature)